106TH CONGRESS
1ST SESSION

S. 117

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

IN THE SENATE OF THE UNITED STATES

JANUARY 19, 1999

Ms. SNOWE introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improved Patient Access to Clinical Studies Act of 1999''.

SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

(a) AMENDMENTS TO ERISA.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income

Security Act of 1974 (29 U.S.C. 1185 et seq.) (as amended by the Women's Health and Cancer Rights Act of 1998) is further amended by adding at the end the following new section:

"SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

''(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not deny (or limit or impose additional conditions on) the coverage of items and services furnished to an enrollee if—

''(1) the enrollee is participating in an approved clinical study;

''(2) the items and services are furnished according to the design of the study or to treat conditions resulting from participation in the study; and

''(3) the items and services would otherwise be covered under the plan except for the fact that the items and services are provided in connection with participation in such a study.

Such a plan or issuer may not discriminate against an enrollee on the basis of the enrollee's participation in such a study.

''(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as requiring a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, to provide for payment for items and services normally paid for as part of an approved clinical study.

''(c) APPROVED CLINICAL STUDY DEFINED.—In this section, the term 'approved clinical study' means—

''(1) a research study approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity (as defined in guidelines of the National Institutes of Health); or

''(2) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, is efficacious, or has any other characteristic of a treatment that must be demonstrated in order for the treatment to be medically necessary or appropriate.''.

(2) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement In-

come Security Act of 1974 (29 U.S.C. prec. 1001) is amended by inserting after the item relating to section 713 the following:

''Sec. 714. Coverage for individuals participating in approved clinical studies.''.

(b) AMENDMENTS TO PHSA.—

(1) GROUP MARKET.—Subpart 2 of part A of title XXVII of the Public Health Service Act (29 U.S.C. 300gg–4 et seq.) (as amended by the Women's Health and Cancer Rights Act of 1998) is further amended by adding at the end the following new section:

''SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

''(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not deny (or limit or impose additional conditions on) the coverage of items and services furnished to an enrollee if—

''(1) the enrollee is participating in an approved clinical study;

''(2) the items and services are furnished according to the design of the study or to treat conditions resulting from participation in the study; and

''(3) the items and services would otherwise be covered under the plan except for the fact that the

items and services are provided in connection with participation in such a study.

Such a plan or issuer may not discriminate against an enrollee on the basis of the enrollee's participation in such a study.

''(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as requiring a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, to provide for payment for items and services normally paid for as part of an approved clinical study.

''(c) APPROVED CLINICAL STUDY DEFINED.—In this section, the term 'approved clinical study' means—

''(1) a research study approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity (as defined in guidelines of the National Institutes of Health); or

''(2) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, is efficacious, or has any other characteristic of a

treatment that must be demonstrated in order for the treatment to be medically necessary or appropriate.''.

(2) INDIVIDUAL MARKET.—Subpart 3 of part B of title XXVII of the Public Health Service Act (29 U.S.C. 300gg–51 et seq.) (as added by section 605(a) of the Newborn's and Mother's Health Protection Act of 1996 and amended by the Women's Health and Cancer Rights Act of 1998) is further amended by adding at the end the following new section:

''SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

''The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as the provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.''.

SEC. 3. EFFECTIVE DATE.

The amendments made by this Act shall apply—

(1) with respect to group health plans for plan years beginning on or after January 1, 2000; and

(2) with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated

in the individual market on or after January 1, 2000.

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